EXHIBIT 28

Case-Specific Report in *Trombley v. 3M*

February 15, 2019

Dr. J.P. Abraham

I have previously submitted three reports in the Bair Hugger litigation; one on June 1, 2017 in the MDL; in the case of *Louis Gareis v. 3M*, on December 18, 2017; and in the *Axline v. 3M* case in September 2018. I rely on and incorporate those reports for my general opinions in the Trombley case (with the exception of any content that related solely to case-specific features of the *Gareis* and *Axline* cases). In my review of photographs of the operating room where Ms. Trombley's surgery took place, I noted airflow obstructions, heat-generating equipment, and several other factors that affect airflow in that room. There are also inevitable flow disturbances caused by movement of staff which occurs during a surgery that will affect the airflow within the room. In this report, I expand on the opinions I expressed in my earlier reports with respect to specific conditions in the operating room where Ms. Trombley's surgery took place that pertain to airflow.

My opinions are based on my education, training, and experience with airflow systems and computational fluid dynamics, as well as my review of the scientific literature. I also rely on the experiments I performed and calculations I completed in an actual operating room, as described in my MDL report. I reserve the right to supplement this case-specific report if I receive additional information relevant to my opinions and anticipated trial testimony in this case.

1. SUMMARY OF OPINIONS

To elaborate on the opinions I disclosed in my earlier reports and testimony, and in addition to those opinions, I express the following:

1. As I have stated previously, there is no evidence that the Bair Hugger disrupts downward airflow, brings pathogens to a surgical site, or is otherwise capable of causing or contributing to surgical infections, and I have found no evidence that the Bair Hugger caused or contributed to Ms. Trombley's development of a surgical infection following her surgery.
2. There are many ways that airflow is disturbed in an operating room, such as the movements of the surgeons and staff, opening and closing of doors, traffic in and out of the room, location and type of surgical lamps, equipment that generates heat and air motion, equipment that impedes airflow from the ceiling supply vents, the locations of room inlet and exhaust vents, and the type of ventilation system (turbulent versus laminar[1]), among many others. Plaintiff's expert Dr. Said Elghobashi did not account for any of these disturbances in his CFD models. Thus, to the extent any of Plaintiff's experts intend to offer opinions about the cause of Ms. Trombley's infection based on the

[1] As Dr. Elghobashi and others have commented, airflow in an operating room cannot be truly "laminar" due to the many obstacles and flow boundaries that cause turbulent eddies to form. When I use the term "laminar" in this report, I do not intend to suggest that true "laminar" flow is ever achieved – rather I am merely repeating it as a descriptive term that appears in the literature on operating room airflow.

work of Dr. Elghobashi and his co-author, Dr. Sourabh Apte, those opinions lack a scientifically valid premise.

3. Dr. Elghobashi did not attempt to adjust his CFD models to reflect the operating room where Ms. Tombley's surgery took place. He did not correct his models to incorporate the number and position of the inlet vents, the position and operation of the exhaust vents, the actual operating room flowrate, the shape and dimensions of the room, the details of the ceiling vents and fans, or the equipment within it. He also did not account for any movement of staff, changes to the number and positioning of staff, opening or closing of doors, traffic within the OR, or temperature differences between the OR and adjoining spaces. Every one of these items is known to disrupt and modify airflow patterns. Again, to the extent any of Plaintiff's experts intend to offer opinions about the cause of Ms. Trombley's infection based on Elghobashi and Apte's work, those opinions are based on an irrelevant set of assumptions.
4. Independent researchers have published computational and experimental results that support the opinions I derived from my own CFD models and experiments. These articles do not support Dr. Elghobashi's opinions, or any opinions that Plaintiff's experts intend to offer based on Elghobashi and Apte's work.

2. OPERATING ROOM AIRFLOW IS DISTURBED BY MYRIAD FACTORS THAT ARE NOT ACCOUNTED FOR IN PLAINTIFFS' COMPUTATIONAL ANALYSES

There are many ways that airflow can be disturbed in an operating room like the one at Bay Park Hospital in Oregon, Ohio where Ms. Trombley's surgery took place. Chief among these are:

1. The position and movement of surgical lamps and other equipment over the operating table
2. The number, position, and movement of the treating physicians and staff
3. The number and positioning of vents which distribute filtered air over the operating table
4. Other obstructions, including surgeons and staff, in the airflow path
5. Devices and equipment that generate heat and exhaust air
6. The positioning of the exhaust vents that draw air from the room, and whether they are powered or passive
7. The presence and location of other vents (supply or exhaust) that exist in the room and their position relative to each other.
8. Opening and closing of doors and traffic in and out of the room

Plaintiffs' CFD models ignore virtually all of these factors. As a result, their models cannot predict airflow trajectories, particle paths, or other airflow features that would have been present during Ms. Trombley' surgery, or in any other surgery.

Published literature demonstrates the importance of each of the above considerations to the constantly changing dynamics of operating room airflow.

The position and movement of obstructions

Among the research supporting this point, [1] was an experimental study that used three different methods to visualize airflow. The methods were Schlieren photography, bubble-generation, and smoke visualization. The authors considered surgical lamps and staff as potential obstructions to the airflow. They found "*The importance however of obstructions such as operating lamps and personnel was shown*." Consequently, the exact position and motion of surgical lights and personnel throughout the surgery are critical for predictive calculations.

More recently, [2] showed not only do lamps matter in determining airflow, but that numerical calculations must be validated. In this study, complementary CFD calculations and experiments were performed to assess the effect of various lamp sizes and shapes on airflow. The key finding was that "*the projected area of a lamp is a good indicator for the infection risk*." Here, the authors use the term "infection risk" as calculated using the ratio of the concentration of particles measured below a surgical lamp compared to a reference concentration. It is not an actual risk of infection to a patient. Consequently, the positioning and movement of lamps throughout the surgery are essential inputs for any calculation which seeks to be predictive. The researchers of [2] used the LES model in the software ANSYS for their calculations. The researchers conclude that particles can be treated as a gas, as was done in my calculations. The researchers also validated their calculations by comparing the results with airflow experiments.

Other recent studies confirm these findings. For instance, [3] found that "*If a vertical laminar airflow ventilation system is utilized, obstacles such as the surgeons' heads and operating lamps become increasingly important. Currently many medical devices that disturb the unidirectional downward flow are installed above the operating area, which can reduce the effectiveness of the vertical laminar airflow ventilation. Moreover, the heat generated by medical devices and surgical team members has a remarkably negative effect on the vertical LAF system. There is a considerable stagnant area behind surgical lamps with large surface areas when they are interposed in the unidirectional down flow systems. This stagnant area may include a high bacteria concentration because it is usually close to the contamination source, such as a surgeon.*" It is noteworthy that the authors of [3] validated their calculations using experiments. Also, the authors of [3] used the calculation software ANSYS and they use streamlines to show airflow patterns.

Another study [4] confirmed the conclusions of [3]. There, the effect of objects like surgical lamps that are positioned above the operating table was shown to be important. It is again noteworthy that the authors of [4] performed their calculations using ANSYS and validated their calculations by comparing the results to experiments.

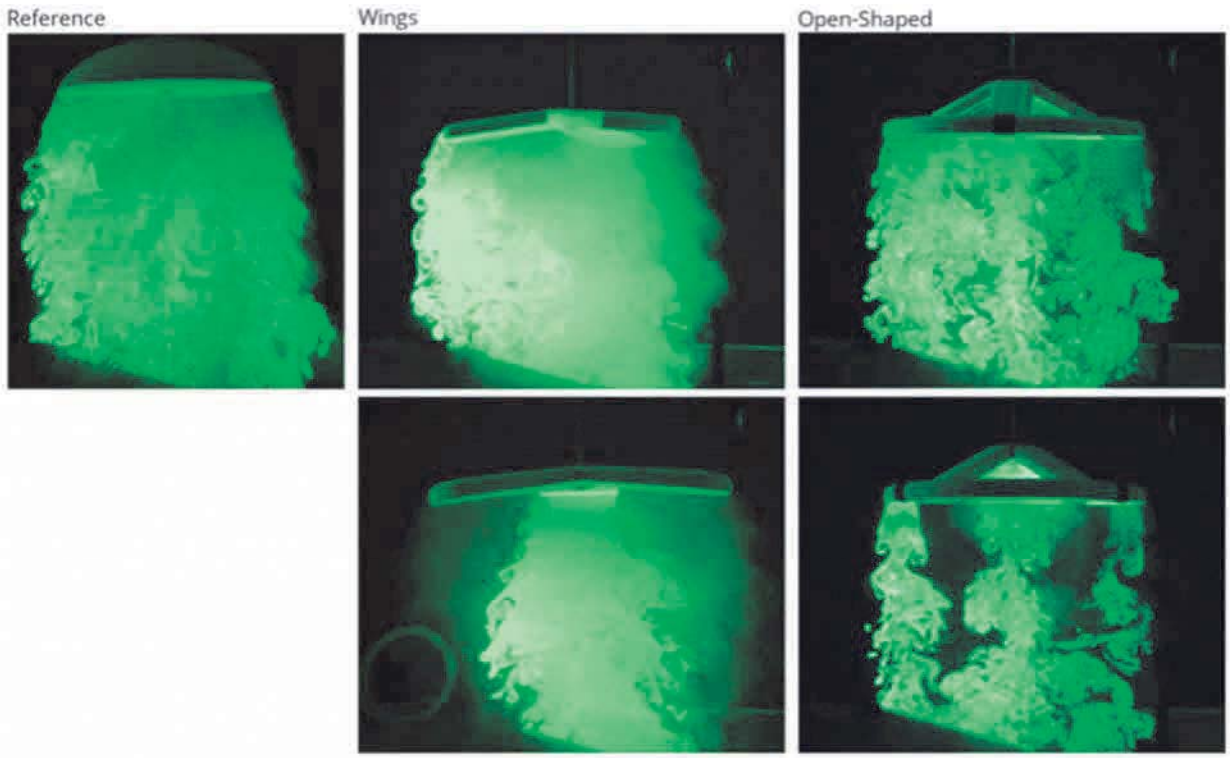
Very recently, [5] provided even more evidence of the importance of the position, size, and movement of surgical lamps. These researchers stated that "*The most important source of airborne contamination in an OR is related to the infectious particles released from the surgical staff*." To assess these particles, the researchers used the software program ANSYS to calculate the airflow patterns. They found that surgical lamps positioned above the operating table have a significant effect on the airflow. They conclude, "*When combined with a closed-shape lamp, laminar air flow results in more than 100 bacteria carrying particles per unit area that settle over the operating table in one hour*."

More research has confirmed the clear fact that surgical lights can impact airflow and that accounting for the position and movement of surgical lights is essential for any airflow predictions. Using experiments, [6] found that when no surgical lights were used, downward airflow from the ceiling passed unimpeded. However, if lights are placed above the surgical location, the downward unidirectional airflow is disrupted and air can recirculate in the surgical field. They also conclude that a light above the surgical site reduced the airflow system's ability to clear the air. Again, this study confirms the importance of the position and movement of lights.

Researchers in [7] used a thermal mannequin and surgical lamps in their experiments. They found that lamps did impact the airflow above the operating table. They also found that thermal plumes from the warm patient may cause higher velocities over the operating table. The authors write "*This study showed a complex airflow distribution in the operating microenvironment of a lying patient. The air distribution may change significantly under various conditions involving the presence of different heat sources, including the surgical lamps, the patient, surgical staff and various monitors in the orthopedic OR. These heat sources will generate various forms of thermal plume, which have great potential to hinder clean airflow to the surgical site…. Using the lamps at horizontal positions may block clean airflow from the LAF system. It is therefore suggested that the placement of lamps should be carefully considered before an operation to ensure that the clean supply air reaches the surgical site…. In addition, the presence of surgical staff may further disrupt the clean air distribution in proximity to a patient in ORs.*" The authors also report that "*the downward airflow from the laminar airflow system <u>varies in each case with different surgical arrangement</u>, such as the position of the operating lamp*." This research shows that no two rooms or two surgeries are alike. These researchers also used air velocity measurements (streamlines) to quantify flow in the room.

The same findings were confirmed by [8] who performed flow visualization experiments in a laminar-air-flow environment with mannequins that represented the patient and the staff. They found that lights significantly disrupt the airflow.

While overhead lights are necessary for performing joint replacement surgery, it is important to recognize the role they can play in disrupting ceiling airflow and circulating particles shed by surgical staff. Visual evidence of these obstructions is provided in Fig. 1 (and listed videos) by the Hermann-Rietschel-Institut (HRI) [9], and provided online by the German Federal Ministry for Economic Affairs and Energy (<u>https://blogs.tu-berlin.de/hri_op-luft/2019/01/04/closer-look-on-lamp-shapes/</u>).



Video 1: Flow Vizualisation of recirculation area under different shaped luminaires

Fig. 1 – The effect of surgical lights on downward laminar airflow systems [9]

What is evident from these many studies is that the positioning and movement of obstructions and equipment and objects that generate heat above the surgical table throughout a surgery have profound effects on operating room airflow. Any predictive calculation would have to account for those effects. Insofar as the Plaintiffs' computational models do not account for the positioning of surgical lamps or their changes during Ms. Trombley's surgery, the exact position and motion of the staff, the presence of heat sources and airflow obstructions above and near the surgical site, they cannot be used to predict particle paths during that surgery.

These studies also demonstrate that ANSYS is widely used by independent researchers to calculate air flow in operating rooms. They further reinforce the importance of validating calculations with experiments. Finally, this research shows that no two rooms or two surgeries are alike. The airflow is different in each situation.

The number, position, and movement of surgical staff

Movement of the surgeons and staff are also important. In [10], a CFD model was used with a RANS algorithm and Boussinesq equation (as in my calculations). In the CFD model, particles were simulated to be released from the surfaces of the staff/surgeons. The researchers found that the simple action of bending from a surgeon can increase particles at the surgical site 250 fold. The study, carried out in a vertical-flow ultra-clean airstream, envisioned the surgeon bending forward and then back up to vertical. The authors validated the CFD calculations by comparison

to an experiment. This study shows that surgeon motion, even a single bend, not only disrupts airflow patterns, it can also increase airborne particle concentrations. This demonstrates that ignoring surgeon motion makes Plaintiffs' CFD calculations non-predictive.

The researchers in [10] also report "*We found that the air supply velocity and the medical lamp position can strongly influence the dispersion of airborne infectious particles and hence the infection risk*" providing added support to the opinions discussed above. This further confirms that the location and movement of surgical lights and surgical staff must be incorporated into any predictive model.

The work in [10] was confirmed by [11] who used CFD methods to study airflow. In the CFD model, simulated particles were released from the simulated surgical team. The authors showed that the position of the surgical staff can have dramatic effects on the concentration of bacteria-carrying particles. In particular, bending surgical staff significantly increased the concentration of simulated particles at the surgical site. The study [11] used ANSYS for the calculations and validated the numerical model using experiments.

In [12], results of another study on the effect of staff movement were provided. There, smoke visualization studies and computational investigations were performed. The study included a laminar air flow surgical room and the movement of a staff member within the room. When staff moved, they found "*the influence on the contaminant concentration is very significant and a substantial increase in the bacteria level around the operating table is found. Around the operating table the bacteria level increased with approximately 25 cfu/m^3*." This study shows that motion of staff cannot be neglected in any attempt to model conditions that may have been present during Ms. Trombley's surgery. The calculations in [12] relied upon vectors/streamlines to indicate flow patterns, no separate particulate trajectory calculations were performed. In this regard, it is a worst case calculation and is the same method I adopted in my analysis.

Similarly, in [13] a computer prediction of airflow in an operating room was accomplished using the ANSYS program. The calculations were validated with experimental data and the analysis corresponded to a unidirectional downward airflow operating room. It was shown that motion of the surgical staff can disrupt air flow near the patient. The calculations were based on an actual operating room that is in service. The authors report that motion "*progressing towards the operating table would cause small and light particles to be released from the person, and this could contaminate the surgical area*." This study also shows that motion of the surgical staff cannot be neglected in any effort to model OR airflow conditions. This study further shows that numerical models should be validated by experimentation. It also demonstrates the capacity of ANSYS to calculate these airflows. Furthermore, this study confirms the use of airflow patterns (streamlines) to show potential paths of light particles in the room.

Other studies, such as [14], have shown that the number and position of the surgical staff matter. This study, which also used ANSYS software and Boussinesq equation, was validated by experiments (using temperature and velocity measurements). The study used ceiling mounting unidirectional airflow and assumed a shedding rate of 4 CFU/s for each staff member. The chosen fluid model was the $\kappa-\varepsilon$ RNG approach, executed by the ANSYS software. The conclusion from the study was that as the number of staff increases from 4 to 10, the

concentration of simulated particles increases at the operating table and at instrument tables. This study shows that it is critical to account for the number and positioning of the staff during the surgery when creating a predictive model. This study also shows that ANSYS can be used for calculating airflow in an operating room, that my buoyancy equation is accepted by the research community, and that CFD models should be validated with experiments.

So too in [15], the researchers report that an increase in the movement and activity in an operating room corresponds to an increase in counts of airborne microorganisms. Such activity was not accounted for in the computational studies associated with the present litigation.

These conclusions were also found experimentally in [16] where the effect of movement and presence of the patient and staff had "*by far the greatest effect on numbers (of bacteria)*."

This body of research demonstrates the necessity of accounting for movement and positioning of the surgical team throughout the surgical procedure for any attempt to build a predictive model of operating room airflow. According to the literature, staff motion and position are predominant influences on airflow and particle dispersion. This body of research also shows that ANSYS is a widely accepted program used for calculating airflow in an operating room and that my methodology is accepted within the scientific community. It is used extensively by researchers for this purpose. Finally, the body of research highlights the necessity of validating numerical calculations using experiments. For all of these reasons, any opinions offered by Plaintiff's experts based on Elghobashi and Apte's work are fundamentally flawed. Their CFD models cannot describe the movement of squame particles shed by surgical staff during Ms. Trombley's surgery.

Door openings and traffic in and out of the operating room

In addition to positioning of airflow obstructions and positioning and movement of surgical staff, the opening and closings of doors affects airflow within the room. While I have not been provided an exact count of door openings and closings during Ms. Trombley's procedure, *any* entries or exits during the surgery would disrupt airflow and the dispersion of bacteria-carrying particles shed by staff. Moreover, entries and exits *before* the surgery could introduce shed particles into sterile areas and on to sterile instruments.

Among the research on this subject is that of [17]. That research team took airborne bacteria samples during 81 orthopedic surgeries, mainly total-joint arthroplasties. They found that "*Laminar Air Flow does reduce the contamination due to more door openings, but does not abolish it*." They also report that "*if the doors are opened at all, the expected number of CFUs increases by 69.3*%". The authors report that unidirectional airflow decreases the CFU by less than 40%. They also report "*The majority of the risk of contamination was introduced with the first opening*." The effects were seen both inside and outside the unidirectional flow area. The effect of door openings on the operating room is two-fold. First, there is a direct disturbance of the air in the room caused by the door opening. Second, door openings often coincide with persons entering the room and bringing contamination. The authors write "*Door opening creates turbulence by diminishing the pressure gradient between two spaces. Turbulent air follows a chaotic, non-laminar pattern which might lead to faster spread of airborne bacteria or*

aerosolized and dust borne contaminants, to the surgical field. We also report a concordant increase in microbial counts with the frequency of door openings."

This finding, of the impact of door openings on airflow, was confirmed by [18]. That study used a numerical calculation technique called Large Eddy Simulation to calculate airflow patterns in a room when a door opens and a person enters into the room. The CFD analysis was compared with experiments to validate the calculations. Furthermore, the calculations were completed using ANSYS. The experiments and calculations show that air from outside the room is pushed very far into the isolation room following the door opening and entrance of a mannequin. Visual evidence from [18] is shown in the image below. Smoke is used to visualize the air brought from one room into the adjacent room. The researchers in [18] used a gas instead of particle transport in their calculations of potentially unclean airflow. This was the approach I also used.

camcorder shot CFD LES

Fig 7. Smoke experiment in the anteroom side. Experimental smoke visualization as compared with simulated smoke drawn by the method of stacked contour maps. This figure is one frame of S4 Video. Again, a certain height interval alone is being lit.

Fig. 2 – smoke images showing unclean air entering into a room [18]

Similar findings were reported in [19] where experiments were carried out with both hinged and sliding doors and a mannequin. The researchers found that in both cases, unclean air was brought far into a room with the entry of staff. Again, smoke was used to show the amount of air brought from one room into the adjacent room. In Fig. 3, there are a series of four images. In (A), the door has not yet opened. In (B), the door has opened outwards (a hinged door swinging to the right of the image). In (C), the person has moved into the room, carrying with them unclean air. In (D), the person is in the room and the door has closed. The unclean air has filled the clean space and extended well past the person (who is now standing still).

The direction of the swinging door does not stop the airflow. In the same study [19], images were taken from the other side of the door. Those images are shown in Fig. 4. Again, unclean air is easily able to enter a clean room and contaminate it.

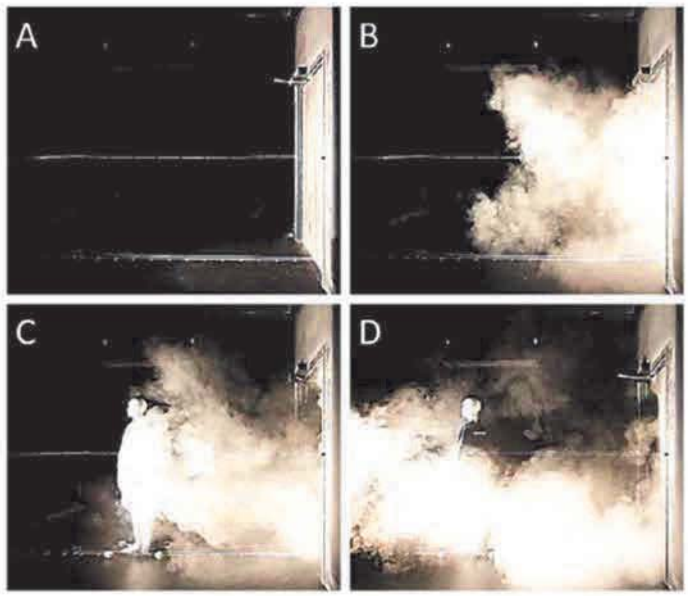


Figure 2. Smoke visualization (anteroom side-view) of the airflow patterns across the doorway generated by the single hinged door and the manikin passage.

Fig. 3 – Four images showing unclean air pass into a clean room as a mannequin moves through a hinged door [19].

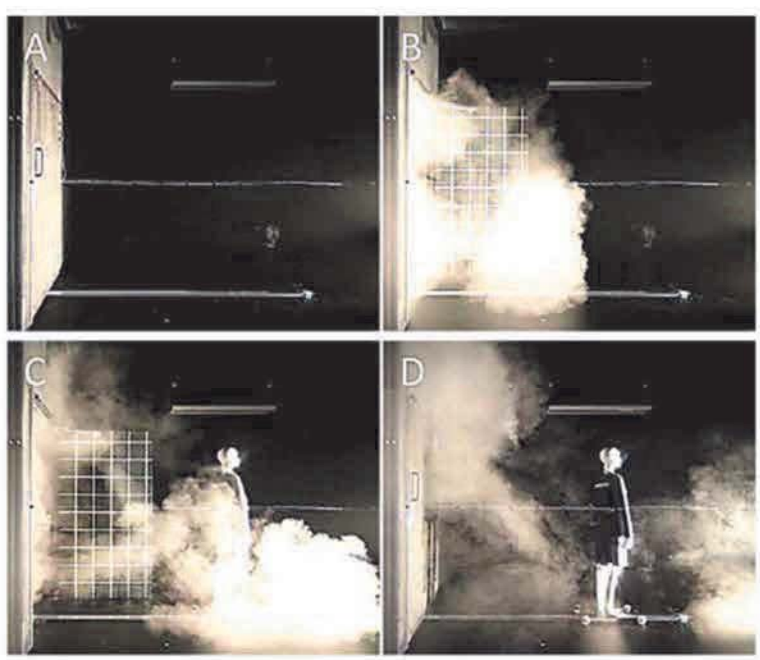


Figure 4. Smoke visualization (isolation room side-view) of the airflow patterns across the doorway generated by the single hinged door and the manikin passage.

Fig. 4 – Four images showing unclean air pass into a clean room as a mannequin moves through a hinged door [19].

It has been thought that sliding doors might mitigate this concern. But as shown in [19] with Fig. 5, unclean air is able to easily pass into a clean room when a sliding door is used.

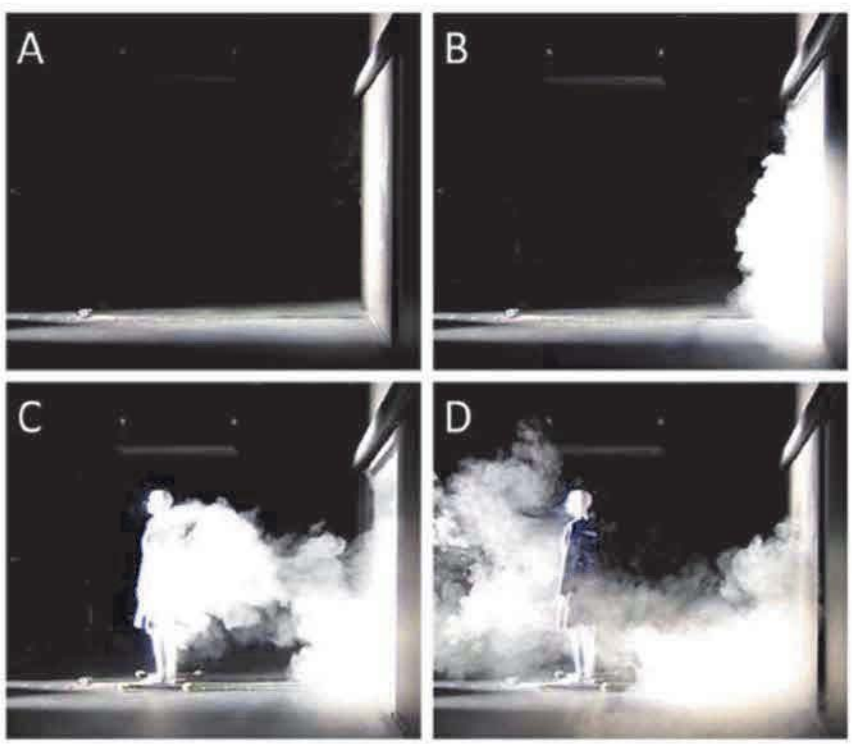


Figure 6. Smoke visualization (anteroom side-view) of the airflow patterns across the doorway generated by the sliding door and the manikin passage.

Fig. 5 – Four images showing unclean air pass into a clean room as a mannequin moves through a sliding door [19].

The motions and door openings shown in Figs. 3-5 were ignored by the plaintiff's experts.

The importance of door openings was also confirmed in [20]. There, a sliding door to a pressurized laminar air flow operating room was opened. These doors are designed to minimize any outside air that may enter into the room. The experiment showed that when the door opens and a person enters the room, they bring with them a large volume of outside air. The experiment is shown in the attached video and images below.

The first image is prior to the sliding door opening. The second image shows the door nearly open. In the third image, air from outside the room is seen to be entering into the operating room, even though the operating room is positively pressurized. In the fourth and fifth images, a staff member is walking through the doorway. It is seen that they bring with them a large volume out outside air. In the final image, the door is closing and outside air is still seen within the operating room.

Sliding Door Closed | Door Almost Open | Smoke Entering Room

Staff Entering | Staff Brings Smoke | Smoke Within Room and Door Closing

Fig 6 – Still images from video showing unclean air entering into an OR [20]

Even with no people entering, just the process of opening a sliding door causes outside air to enter into the operating room. As shown in the sequence of six images below, despite the use of a sliding door (designed to minimize incursion of outside air) and despite a pressurized operating room (also designed to repel outside air), even when no staff pass through the doorway, outside air enters the room. The intrusion of air would be even more significant with swinging doors (as

in Ms. Trombley's case), if proper pressure were not maintained with the operating room, or if a staff member entered through the doorway (which may have occurred during Ms. Trombley's surgery).

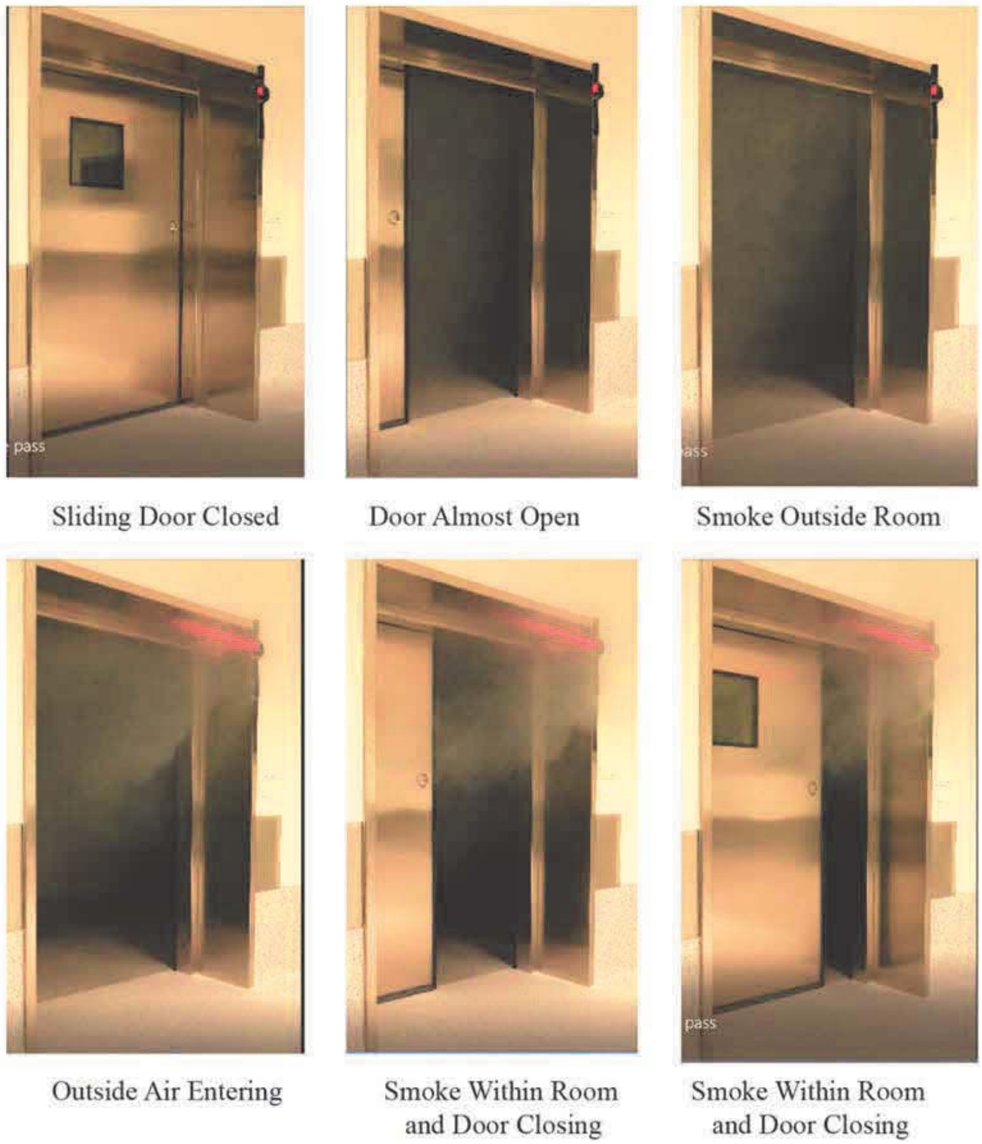


Fig. 7 – Still images from video showing unclean air entering into an OR [20]

Further confirmation of the importance of operating room door openings was provided in [21] where door openings were often able to defeat the positive pressure of the operating room.

Another study, that used ANSYS software and validated the work with experiments, confirmed that even when the rooms are pressurized to mitigate the passage of outside air, it still is able to enter a room [22]. Images from that study are shown in Figure 8. There, the "clean" room is on the right and the "unclean" space is the left. The colors indicate the concentration of outside air. There are a series of 6 images. In the top two images, a door is opened. In the second row of images, a simulated person (indicated by the white block) enters the room, carrying contaminants

from the outside space. In the last row, the door closes and the contaminants remain in the room, surrounding the person that entered. The research of [22] used the same software and particle tracking approach that I used in my general causation calculations.

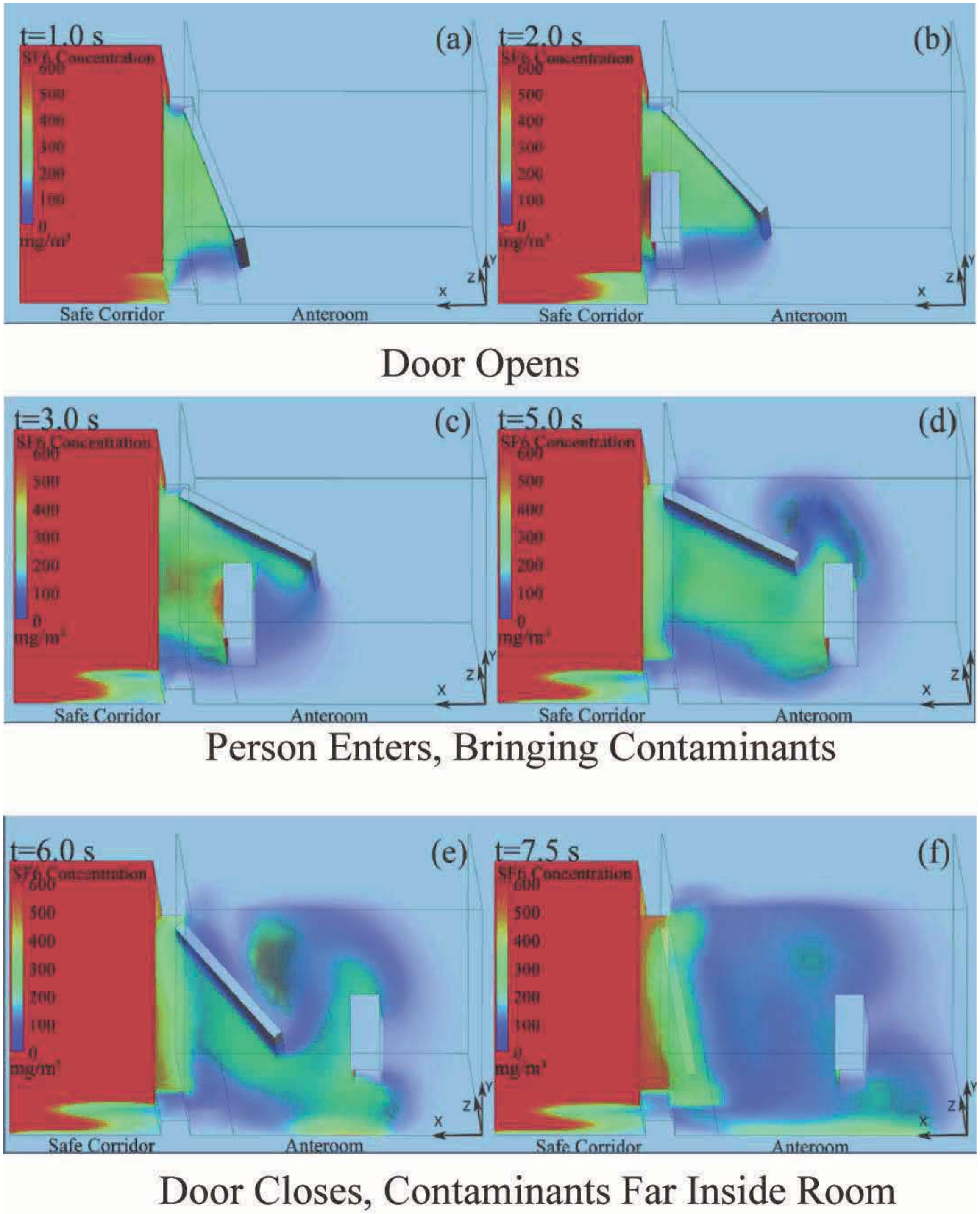


Fig. 8 – Contaminants entering a room when a door opens (from [22]).

These findings show that even for systems specifically designed to prevent outside air intrusion, it happens every time the operating room door is opened. Because of their obvious impact on

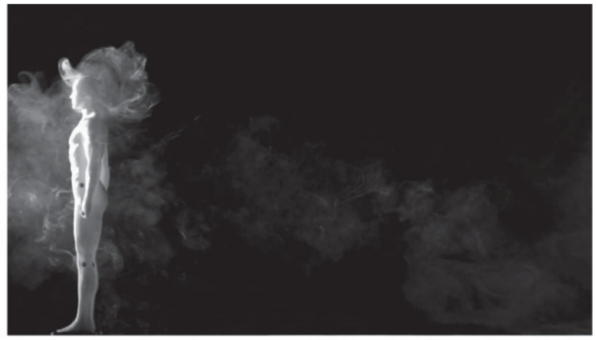
operating room airflow, door openings and personnel traffic must be included in any attempt to predict through CFD the movement of airstreams and particles during Ms. Trombley's surgery. Because the Plaintiffs' CFD models do not do this, they cannot predict the airflow patterns, pathways, or positions of airborne particles that may have been present during Ms. Trombley's surgery.

In [23], experiments were carried out on dust and airborne bacteria levels in a ceiling vented HEPA filtered OR with floor exit vents. 82 microbial samples were made with both active and passive sampling techniques. Airborne dust was measured with a light-scattering dust sensor. During the surgeries, logs were made of the number of door openings, length of surgery, use of various medical devices, etc. The researchers found that door openings were negatively associated with dust particles but were positively associated with increases in bacteria levels. They write "*As expected, air microbial contamination was mainly related to human activity. Independently of the plate position and sampling method (active/passive) bacterial counts were positively associated with door-opening frequency, taken as an index of staff and visitor movement to and from the operating room*."

These results reinforce those of [24]. There, ANSYS was used to calculate the effect human walking has on the air in a room. The authors state *"Our findings show that the human walking disturbs the local velocity field with wake formation."* The authors' calculations, which were validated by experiments, show a wake extended from a person as they pass through a room, similar to the wakes found in [18-21].

Yet another study using flow visualization showed that a moving person carried with them a wake of air. That wake continues past the person even after they have stopped moving [25]. Fig. 9, which is taken from their study, shows a trail of air is brought into a room by a walking mannequin. As the mannequin moves from right to left, a traveling mass of air is brought with them. When the mannequin stops, the unclean air passes forward of the body and makes any contamination worse. The unclean air in front of the body persists even after the person has stopped moving.

Starting to Move

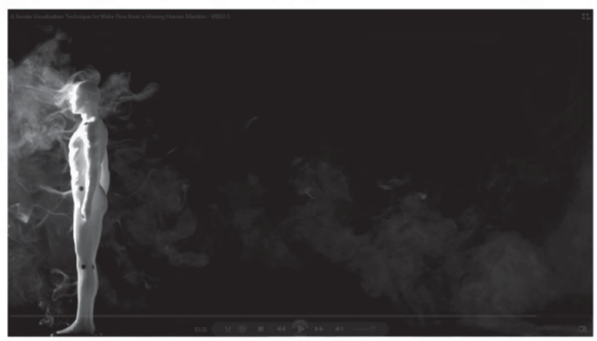


Stopped Movement

Continuing Movement

Stationary

Continuing Movement



Stationary

Fig. 9 – Photographs of an experiment showing air brought along with the motion of a human [25].

A separate set of images from another experiment confirms this fact, humans bring air with them as they walk and carry outside air into an OR. Any predictions of airflow must include such motion. The annotations within the images of Fig. 10 are from the authors of that scientific study.

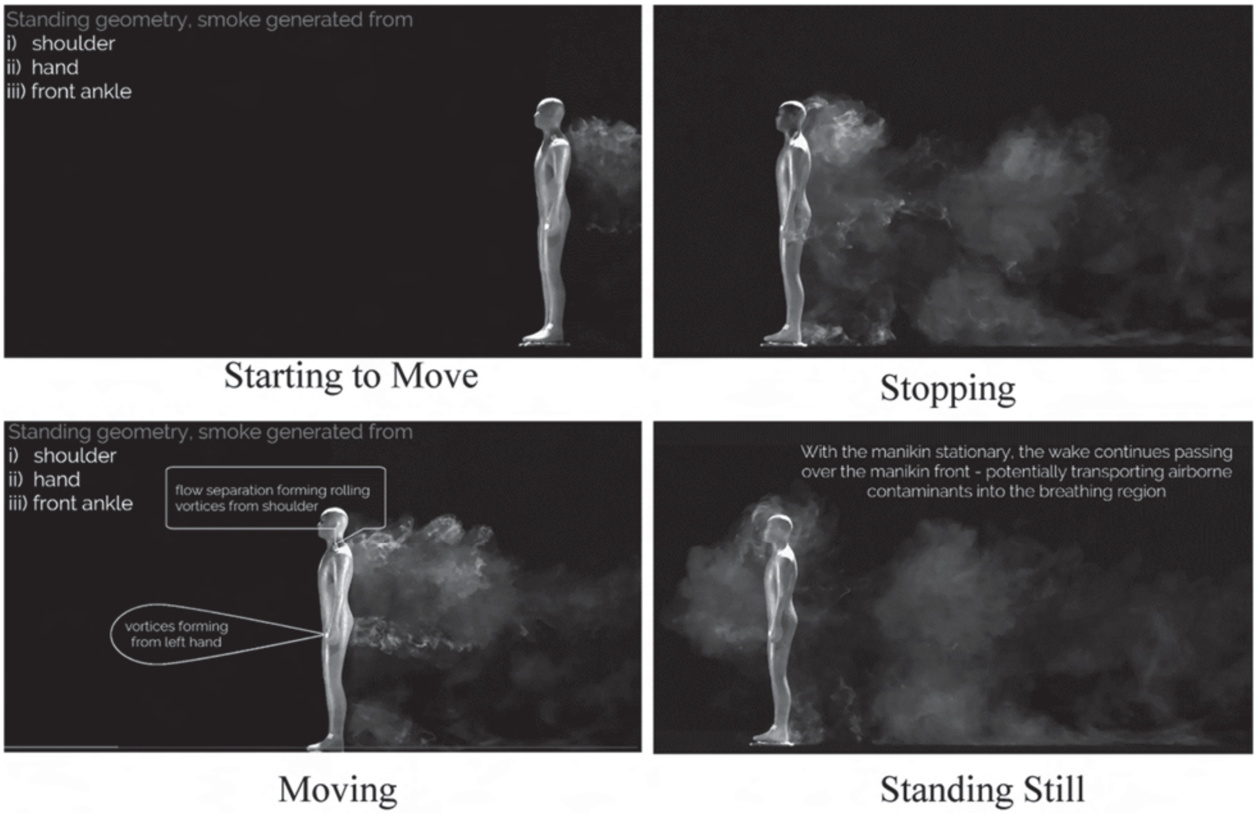


Fig. 10 – Photographs of an experiment showing air brought along with the motion of a human [25].

In [26], a validated calculation using ANSYS was performed on the effect of door openings on bacteria within a positive pressure OR. It was found that even when pressurized, "*the ventilation system fails to maintain the required positive-pressure, which results in the dispersion of infectious particles into the OR.*" The authors also state, "*This study indicates a significant relationship between OR door-openings and room pressure as well as contaminant level. Results show that the airflow movement from the doorway considerably affects the control of airborne contaminant diffusion. Door-opening led to a breakdown in isolation conditions and caused dispersion of infectious air into the OR.*"

The effects of door openings have also been demonstrated in other research. For instance, [27] performed experiments in positive pressure operating rooms and found that measured air particle counts increase when doors are opened.

Also, [28] found that the number of door openings in the operating room and surgery duration were significantly associated with increased bacteria in the operating room. Within the "ultraclean" zone, the number of staff members was significantly associated with increased bacteria load, results were presented for 20 door openings and greater.

Yet another study [29] was performed that also used ANSYS to study airflow in operating rooms. The study matched an actual operating room (St. James University Hospital, Leeds). The inlet was positioned above the surgical site. Two surgeons, a patient, the operating table and

three instrument tables were included in the analysis. Boundary conditions were based on experimental measurements in the operating room and on flow visualization experiments. The calculation was validated by measurements of air speed in the operating room. An anemometer was used to collect air velocity data. In the calculations, pressure differences between the room and an open door were varied from equal pressures to an excessive pressure level (20 Pa). Streamlines were used to track airflow patterns. The researchers found that when the pressure difference between the OR and the surroundings decreases, the ventilation system is not able to provide its protective effect.

Another recent study [30] on the impact of door opening considered a process wherein a sliding door opens and closes over an 18 second period. The opening requires 7 seconds. The door is held open for four seconds, and the closing requires 7 seconds. The operating room is pressurized and different room temperatures are studied. It was found that even when the room is pressurized, unclean airflow from adjacent spaces will enter. The calculations used CFD and were validated with experimentation. The authors find that any temperature difference between the operating room and the adjoining room creates a large vortex which brings fluid very far into the surgical room. Even temperature differences as small as 1 degree can defeat the positive pressure of the operating room. These findings occur without any motion of staff which is known to make infiltration worse. Results from [30] are shown in Figs.11 and 12.

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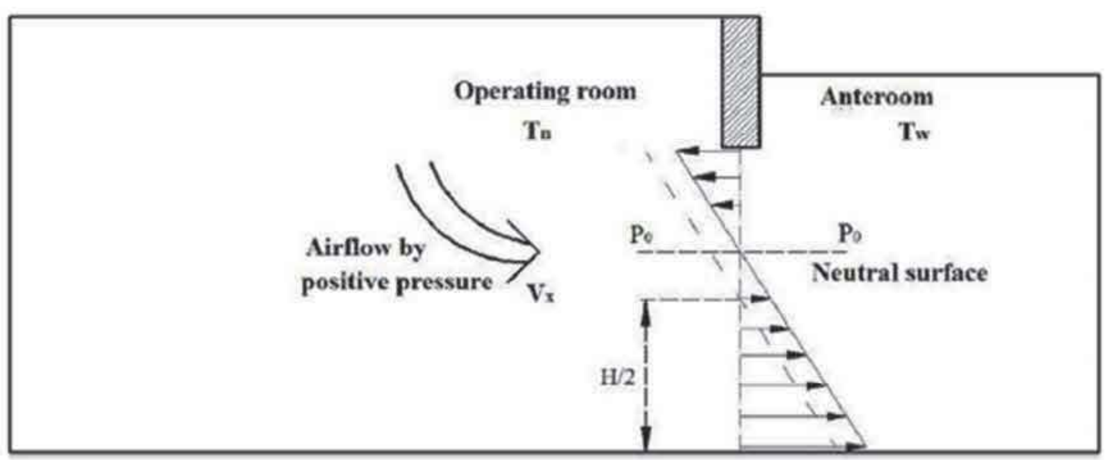

Fig. 2. Schematic diagram of airflow exchange between operating room and anteroom with comprehensive effect of temperature difference and pressure difference.

Fig.11 – Image from [30] showing how outside air can enter an operating room, even when positively pressured.

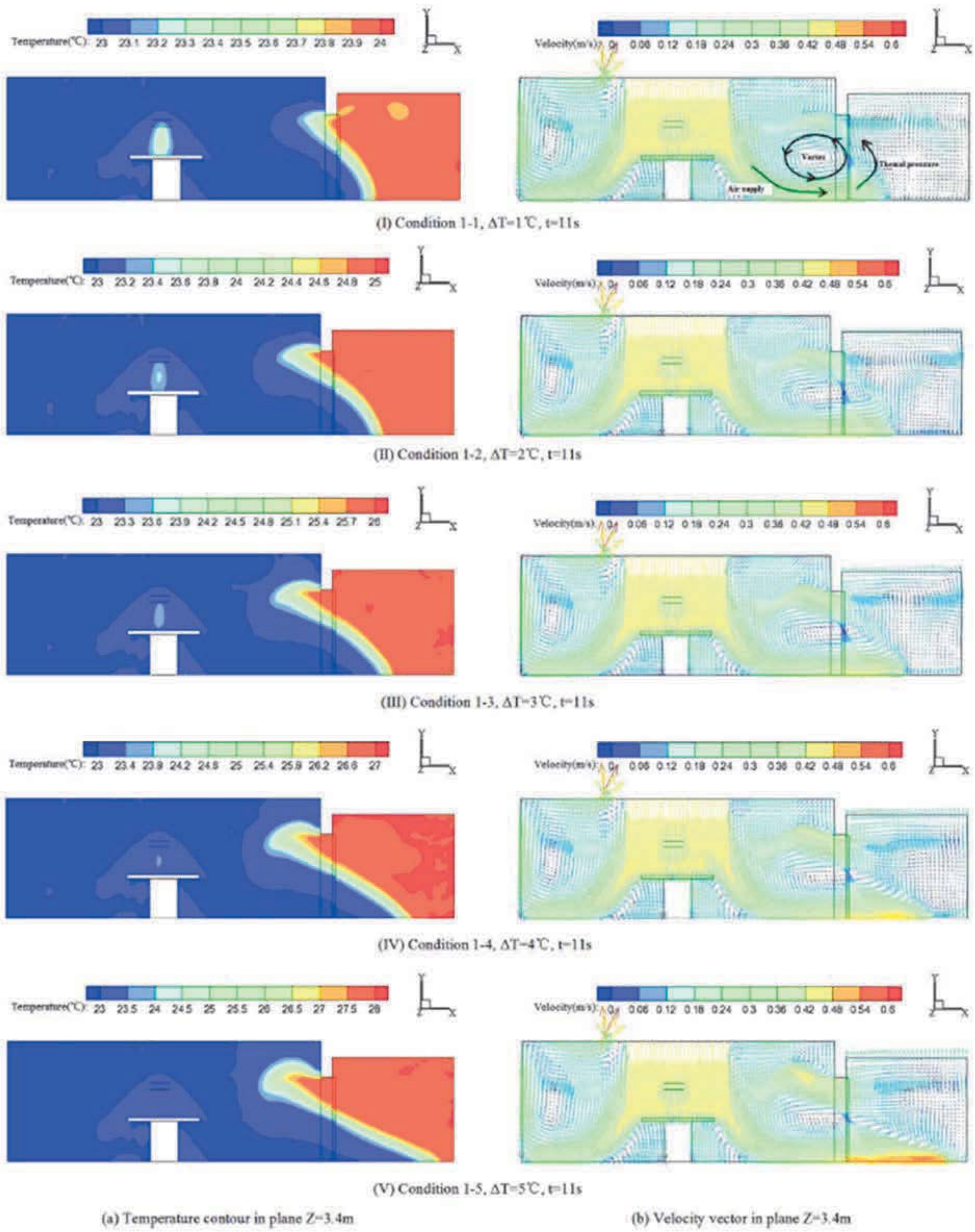

Fig. 12 – Image from [30] showing outside (red) air entering an operating room even when positively pressured. The air flows out of the room at the floor and into the room at the ceiling.

This background shows that every operation is different. These studies demonstrate not only the significant impacts of door openings on operating room airflow, but also that ANSYS software is

a reliable tool to calculate airflow in this setting. Elghobashi and Apte did not account for door openings and traffic, and did not use ANSYS.

This literature also demonstrates the importance of experimental validation for airflow calculations. All but one of the independent research studies performed a validation experiment. The one study that did not validate was a self-described "pilot study." The lack of validation is a major shortcoming in Elghobashi and Apte's work.

Surgeon breathing is another potential vector for pathogens to enter the sterile field. Visual evidence of breathing is provided by the Hermann-Rietschel-Institut (HRI) [9], and provided online by the German Federal Ministry for Economic Affairs and Energy (https://blogs.tu-berlin.de/hri_op-luft/2019/01/04/closer-look-on-lamp-shapes/).

Fig. 13 - Photographs showing airflow before and during surgeon breathing [9]

Summary statement on motion, doors, and obstructions, etc.

Taken together, this body of research clearly demonstrates the importance of factors within the operating room that must be considered, including the positions and movement of the staff; the specific details of the room including, but not limited to the position, number, and type of the vents; the location and movement of surgical lights; the occurrence of door openings/closings; and the presence of medical equipment that can deflect flow or cause plumes above the operating table. Insofar as these cause major effects on the airflow and can impact air quality within the operating room, they must be considered throughout the surgery by any calculation which claims to be predictive.

As I have stated previously, in my CFD calculations for the Model 750 and Model 505, I did not account for door openings, movements of staff, changes to the position and movement of the surgical lights, among many other factors shown to impact airflow in the literature discussed above. That is because the purpose of my calculations was not to predict the dispersion of airborne particles in a particular plaintiff's case, but rather to determine whether the Bair Hugger disrupted the downward flow of air over the surgical table under the conditions set forth in my model, setting aside the countless airflow disruptions from other sources that would occur during a typical surgery. Under the conditions of my calculation, air from beneath the operating table or

from the Bair Hugger itself does not disrupt the downward air flow. These conclusions are verified by physical experiments which took place in the same operating room that is modeled in my calculation. They are also supported by independent researchers (for instance [32]) who concluded "*Airflow caused by forced air warming is well countered by downward laminar airflow from the ceiling*."

In addition to the above discussion of blockages, movement, surgical lamps, doors, heat generating devices above the surgical site, and presence, number and position of staff, so too does the HVAC system impact the airflow within the operating room. Among the details that must be accounted for in any predictive calculation are the number and location of the inlet vents (in the ceiling); the flowrate through the ventilation ducts; the number and position of the exhaust vents which allow air to exit the room, and the operating mode of the exhaust vents (passive or active); the size of the room; the shape of the room; and the actual ventilation flowrate that enters the room. It should also be noted, based on the work of Memarzadeh, that excessive velocity from ceiling ducts could overwhelm the patient's protective surgical plume and impinge particles on the surgical wound.

A summary of the scientific literature discussed above, along with the studies performed by Plaintiffs' and Defendants' experts, is provided by the following table. Of the more than 30 studies listed here, they strongly attest to the importance of validation. They also strongly support the importance of the position and movement of people, blockages, opening/closing of doors, shape and size of the room, positioning of the inlet and outlet vents, temperature difference between the operating room and the adjoining rooms and the pressure difference between the operating room and the adjoining room.

Ref.	Method or Software Used	Issue Considered	Findings	Experiments or Validation?
[1]	Experiments	Air Obstructions	The position and movement of obstructions, such as lamps and personnel matter.	Yes
[2]	ANSYS LES	Air Obstructions	The position and movement of obstructions such as lamps matters	Yes
[3]	ANSYS	Air Obstructions	The position and movement of obstructions, such as lamps and personnel matter.	Yes
[4]	ANSYS	Air Obstructions	The position and movement of obstructions, such as lamps and personnel matter.	Yes
[5]	ANSYS	Air Obstructions	The position and movement of obstructions, such as lamps and personnel matter.	Yes
[6]	Experiments	Air Obstructions	The position and movement of obstructions such as lamps matters	Yes

[7]	Experiments	Air Obstructions	The position and movement of obstructions, such as lamps and personnel matter.	Yes
[8]	Experiments	Air obstructions	The position of lamps has a major effect on airflow in surgical region.	Yes
[9]	Experiments	Air obstructions and surgeons	Obstructions and surgeons disrupt airflow and bring pathogens to the surgical site	Yes
[10]	RANS CFD	Staff Movement	Staff movement changes the airflow in room.	Yes
[11]	ANSYS	Staff Movement	Staff movement changes the airflow in room.	Yes
[12]	RANS CFD	Staff Movement	Staff movement changes the airflow in room.	No (“pilot study”)
[13]	ANSYS	Staff Movement	Staff movement changes the airflow in room.	Yes
[14]	ANSYS	Staff Movement	The number, position, and movement of staff matter	Yes
[16]	Experimental	Staff Movement	The number, position, and movement of staff matter	Yes
[17]	Experimental	Door Openings	Door openings disrupts airflow within room, brings unclean air into room.	Yes
[18]	ANSYS	Door Openings	Door openings disrupts airflow within room, brings unclean air into room.	Yes
[19]	Experimental	Door Openings	Door openings disrupts airflow within room, brings unclean air into room.	Yes
[20]	Experimental	Door Openings	Door openings disrupts airflow within room, brings unclean air into room.	Yes
[21]	Experimental	Door Openings	Door openings disrupts pressure within room.	Yes
[22]	ANSYS	Door Openings	Door openings disrupts airflow within room, brings unclean air into room.	Yes
[23]	Experimental	Door Openings	Door openings disrupts airflow within room, brings unclean air into room.	Yes
[24]	ANSYS	Staff Movement	Staff movement changes the airflow in room.	Yes
[25]	Experimental	Staff Movement	Staff movement changes the airflow in room.	Yes
[26]	ANSYS	Door Openings	Opening Doors disturbs the airflow in an operating room	Yes

[27]	Experimental	Door Openings	Opening Doors disturbs the airflow in an operating room	Yes
[28]	Experimental	Door Openings	Door opening and number of staff affects clean air in OR	Yes
[29]	ANSYS	Door openings and positive pressure effects	Opening of doors and reduction of pressure causes contamination at surgery site	Yes
[30]	RANS CFD	Door openings and temperature differences	Any temperature differences between an OR and the adjacent rooms cause unclean air infiltration	Yes
[31]	Plaintiff's Proprietary CFD	No motion, no doors, no changes to staff, movement of equipment, other blockages above surgical site, different inlet and exhaust vents from actual OR. FAW does disrupt downward air flow.		**No**
[32]	Experimental	Effect of FAW	FAW does not disrupt OR airflow	Yes
[33]	ANSYS	Position of Vents	Position of outlet vents matters	Yes
[34]	ANSYS	No motion, no doors, no changes to staff, movement of equipment, other blockages above surgical site, different inlet and exhaust vents from actual OR. FAW does not disrupt downward air flow.		Yes

3. SURGICAL ROOM DETAILS

Obstacles, heat-generating equipment, venting blockages and venting locations

As discussed here, the details of the OR matter, and will matter throughout an entire surgery like Ms. Trombley's. Some details that I have already discussed include the number, position, and movement of staff in the OR; the movement and positions of the surgical lights; the existence, position, and movement of any obstructing or heat-generating components above the surgical site; the opening of doors; the pressure and temperature within the OR and the adjoining rooms; the exact position of inlet vents the exact position of exhaust vents; the operating mode of the exhaust vents; the flowrate of filtered air into the room; and the shape and size of the OR. As noted, insofar as none of the simulations carried out by either Plaintiffs' experts has accounted for these factors, they are not predictive.

Some examples of the specific nature of the actual operating room in Ms. Trombley's case are shown in the following figures. The images, taken as photographs during a January 2019 visit are used to show the complexity of the actual operating room. For instance, in the following figures, surgical boom lights and flat-screen monitors are seen above the surgical table region. These create obvious obstructions for the air flowing from ceiling vents. It is not just the presence of these lights and monitors that is important, it is also their movement during surgery. The studies that were mentioned earlier in this report point to the importance of how the position and orientation of the lights affect flow. Since the position and orientation would change during surgery, any predictive calculation would have to account for such changes.

Fig. 14 – View of ceiling and lights above surgical site, Trombley OR

Fig. 15 – View of ceiling and lights above surgical site, Trombley OR

Fig. 16 – View of ceiling and lights above surgical site, Trombley OR

In addition to these blockages, which are directly in the airflow pathway between the ceiling and the surgical sites, there are other obstructions that impact airflow. Examples are shown in the following figures.

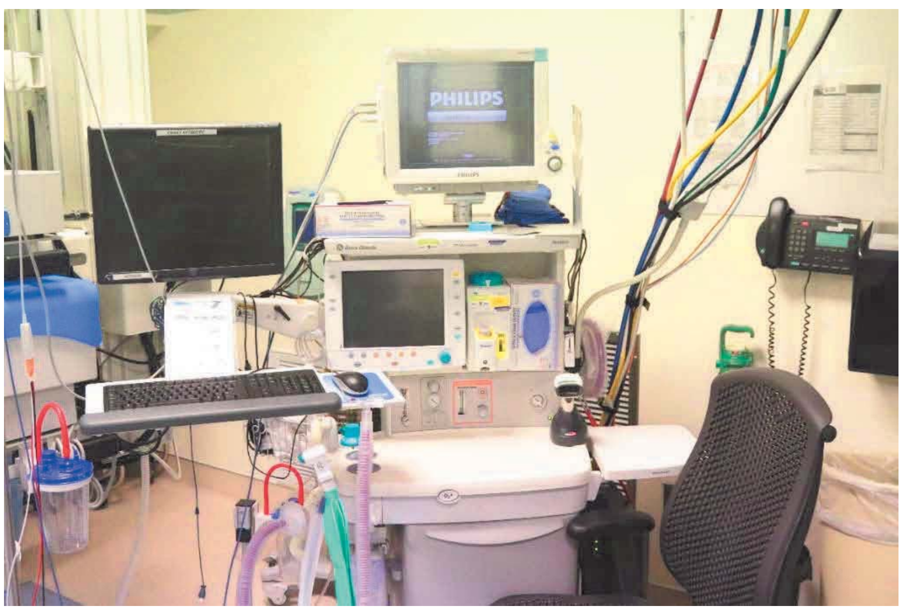

Fig. 17 – Photograph 1 of equipment within the Trombley OR.

Fig. 18 – Photograph 2 of equipment within the Trombley OR.

Fig. 19 – Photograph 3 of equipment within the Trombley OR.

Not only does equipment cause airflow disturbances, but much of it creates its own heat and airflow. This is evident from the photographs taken during the visit to the operating room in January 2019. Some examples of heat and airflow generating equipment are shown in the following images.

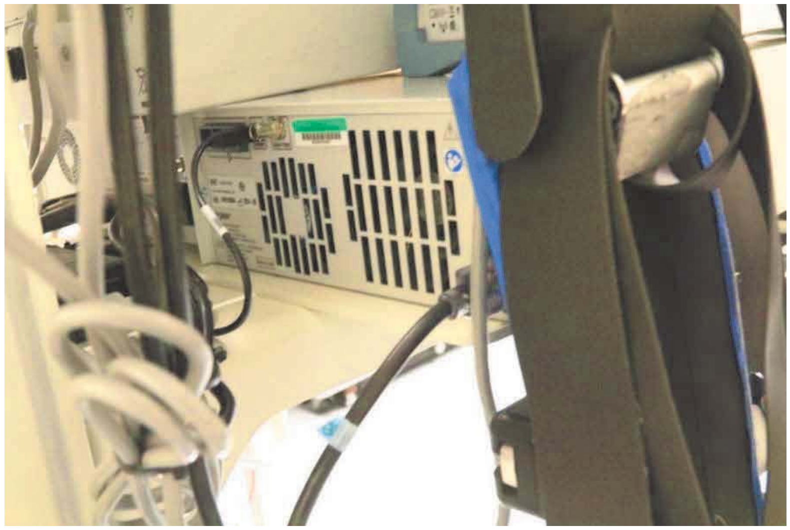

Fig. 20 – Photograph 1 of heat and airflow generating equipment

Fig. 21 – Photograph 2 of heat and airflow generating equipment.

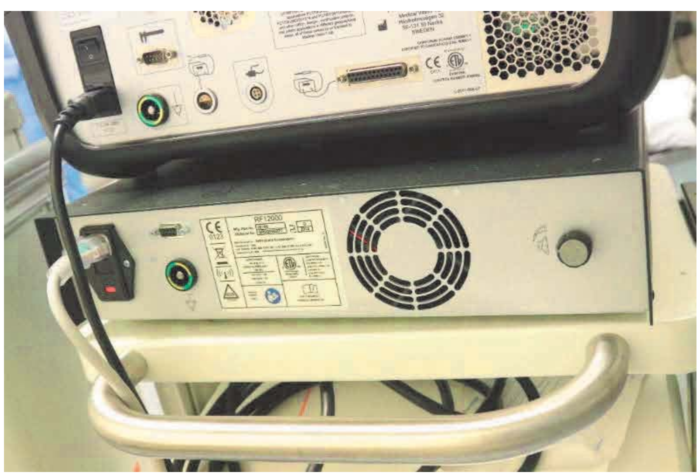

Fig. 22 – Photograph 3 of heat and airflow generating equipment.

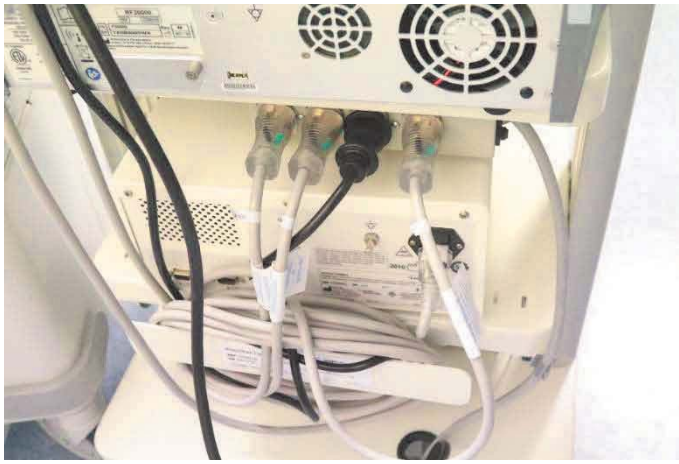

Fig. 23 – Photograph 4 of heat and airflow generating equipment.

None of such airflow causing machines were included in Plaintiffs' CFD models.

I understand that the equipment observed during the OR site visit in January 2019 may not be the same equipment used in Ms. Trombley's procedure in December 2011. Nonetheless, it is my understanding that the equipment shown in the inspection photographs is typical of the equipment used during orthopedic implant procedures.

Another major issue with the Trombley OR, and also not included in any of the plaintiff analysis, is the blockage and positioning of the wall vents. The following images show the wall vents and nearby objects such as doors, apparent waste receptacles, or other equipment that interferes with airflow. Of course, movable objects such as medical equipment or waste receptacles may or may not be in the same position as during the Trombley surgery, but this fact points to the difficulty of recreating actual airflow patterns which occurred when such information is needed.

Fig. 24 – Supply vent obstructed by sidewall and door

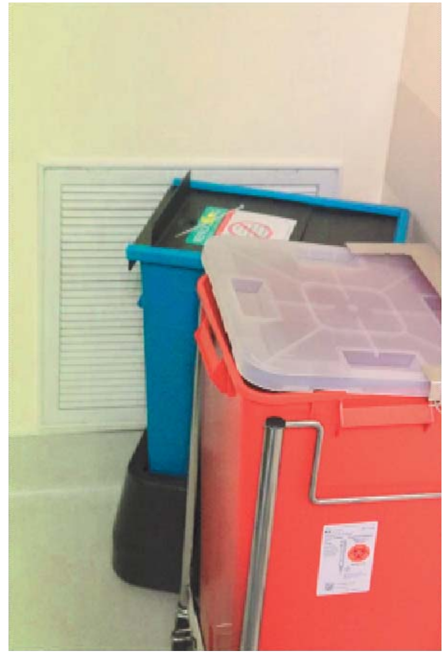

Fig. 25 – Supply vent blocked by obstacles

Fig. 26 – Supply vent blocked by obstacles

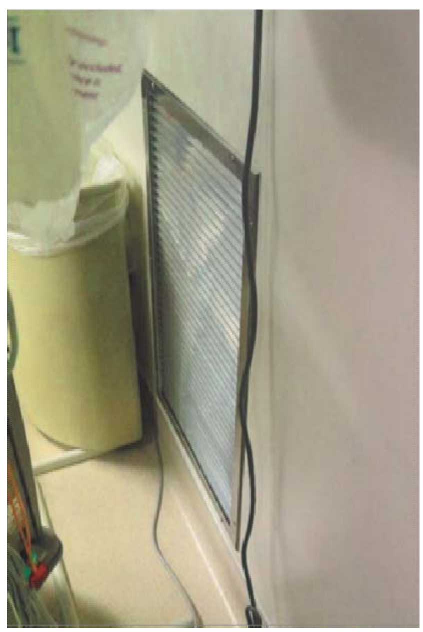

Fig. 27 – Return vent blocked by obstacles

Fig. 28 – Supply vent blocked by obstacles

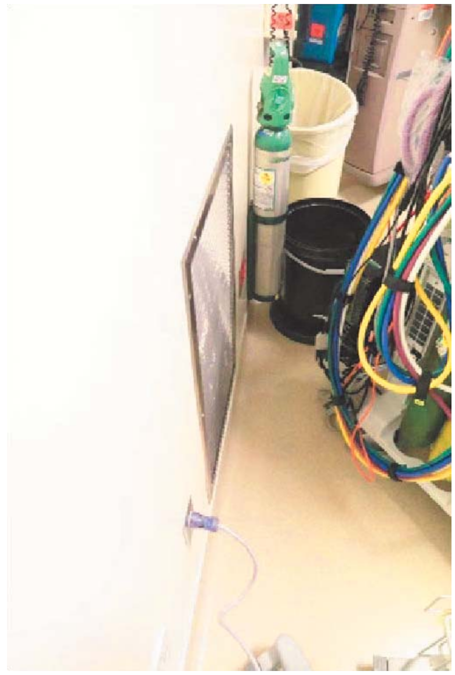

Fig. 29 – Return vent blocked by obstacles

It further appears that the walls contain supply and return vents that are adjacent to each other. I am informed that the white vents are additional supply vents, while the silver vents are returns. The positioning of supply and return vents next to each other on the same wall creates airflow turbulence which affects the flow within the room. As seen in the figure, the two vents (colored white and silver) appear to be separated by approximately ~1-3 feet. Air flow passing through the vents creates what is called a free shear layer. These flows are always turbulent and in fact they amplify turbulence [35-36]. Consequently, these vent positions contribute to flow maldistribution within the OR and guarantee high levels of turbulence. Furthermore, these vents were not included in the plaintiff's analysis.

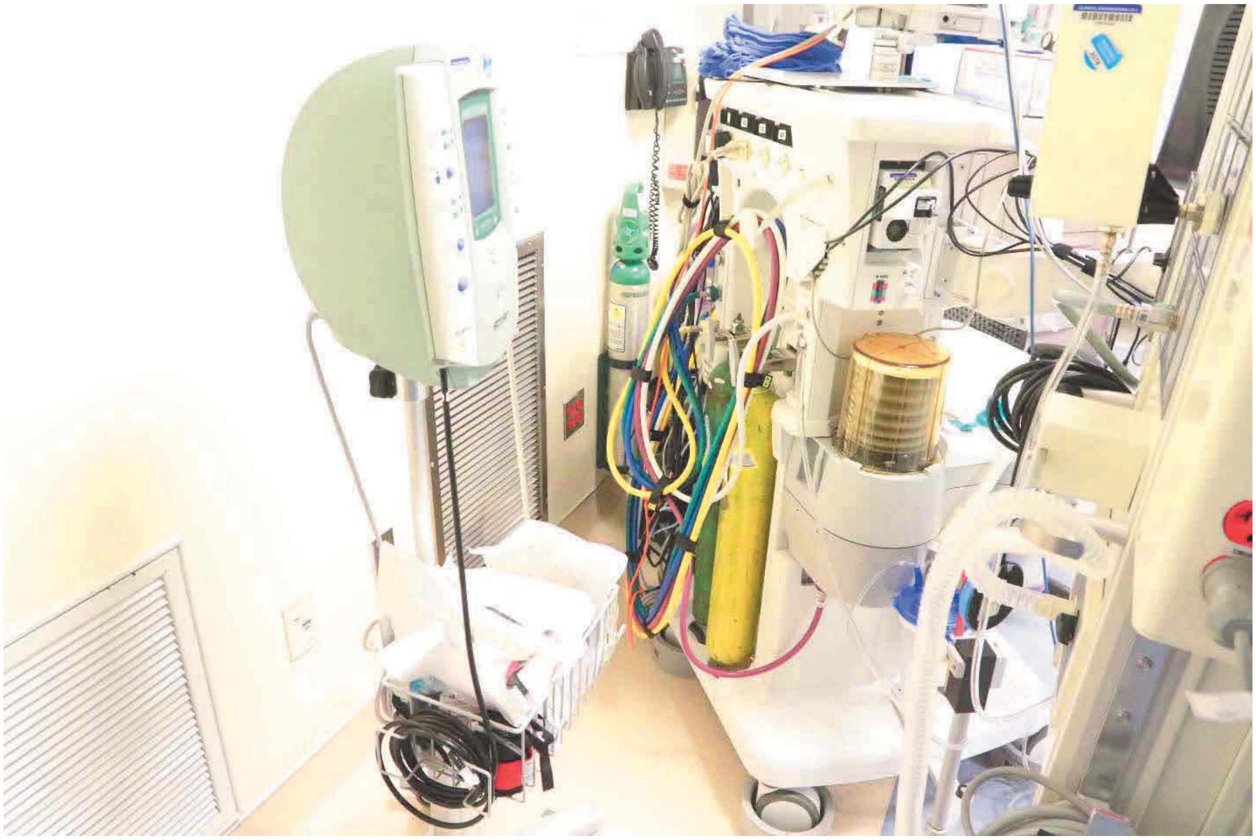

Fig. 30 – Adjacent and obstructed wall vents.

Incomplete knowledge of the thermal and flow conditions during the surgery

As already stated in this report, the flow pattern entering the room and the temperature within the room impact the airflow patterns. In order to properly calculate instantaneous airflow within the operating room, the pattern of flow entering the room must be known. This requires knowledge of the velocity distribution at the supply vents in the ceiling (and any supply vents which may exist on the walls). It is certain that the flow would not be uniform and unidirectional (as assumed in calculations performed by plaintiff's expert). Measurements of the velocity distribution at the supply vents can be made with low-cost commercially available air-velocity probes – but such measurements have not, to my knowledge, been performed.

Also, the temperature of the air from the supply vents, the temperature distribution, the temperature within the operating room, and the temperature difference between the operating room and adjoining rooms with doors has an impact on the flow. It has been shown that such temperature information critically defines the patterns of airflow (hot air rises, cool air sinks) and would have to be incorporated into a predictive analysis. The plaintiff's experts did not include these factors, even though he could have.

Incorrect dimensions of the room, surgical equipment, and vents

Finally, the shape and size of the room, the location of both supply and exhaust vents all dictate the airflow patterns. Insofar as the plaintiff's experts have not performed any calculations for the Trombley OR, the calculations are not able to provide predictive information about what happened during a surgery there.

It is for these reasons that a predictive airflow calculation of a past event, with unknown inputs, is not possible.

4. REBUTTAL OF DR. JARVIS

In his expert report, Dr. Jarvis claims that there is no possibility for the HVAC system to have contributed Ms. Trombley's infection. He bases this opinion on a review of HVAC "system operating manual" for the HVAC system installed in the Bay Park OR where the surgery took place. However, the HVAC documents show a supply system that differs significantly from that considered in the Elghobashi and Apte CFD models – rendering their calculations irrelevant for the Trombley OR. Furthermore, the HVAC documents do not provide information about the velocity or temperature distribution of flow that enters from the ductwork into the room and Dr. Jarvis presents no measurements of the airflow entering the room through the supply vents, their temperature distribution, or flow uniformity. Consequently, his referenced material provide no basis to support his opinions. Further, for all the reasons discussed throughout this report and in my previous reports, Dr. Jarvis reliance upon the Elghobashi and Apte CFD models is misguided. Those models cannot support his opinion that the Bair Hugger caused Ms. Trombley's infection.

5. CONCLUDING REMARKS

In summary, the published literature demonstrates that there are many disturbances that can affect operating room air patterns. A number of those disturbances would have been present during Ms. Trombley's surgery, including the position and movement of surgical lights, the number, position, and movement of surgical staff, the opening and closing of doors, the shape of the room, the size of the room, the actual ventilation flowrate, and the presence of other equipment that heats or disturbs the air, the temperature of the air entering the room and the temperature distribution both within the room and between the room and adjoining spaces, and the positions and type of inlet and exhaust vents. Elghobashi and Apte ignored these factors, and their models therefore cannot predict what happened during Ms. Trombley's surgery. Any reliance on Elghobashi and Apte's work to infer specific causation in Ms. Trombley's case would be invalid and misguided.

Computational fluid dynamics is limited to answering very specific questions. Computational fluid dynamics as performed in this case ignores the major disturbances of airflow, such as the position and movement of the surgical lights or other obstructions, the position and movement of the surgical team, opening and closing of doors, the flow and temperature patterns of air exiting the vents, and the position and strength of heat or flow generating equipment. Insofar the computational model differs from the real-world in the positioning of ceiling vents that provide air to the room, the positioning of return vents that allow air to leave the room, the type of air exhaust vents (passive vs. powered), the shape of the room, the size of the room, the position and movement of equipment which affects air flow in the room, and the position and movement of staff, it cannot be predictive. Computational fluid dynamics cannot predict the trajectory of a bacterium or skin squame when the most important factors are ignored. Thus, the Plaintiff's CFD models cannot be used to show where particles would have traveled or landed during Ms.

Trombley's surgery, and do not support the Plaintiff's claim that the use of the Bair Hugger during her surgery caused or contributed to her development of a surgical infection.

I declare under penalty of perjury that the foregoing is true and correct.

J.P. Abraham, Ph.D.

References

[1] Whyte W, Shaw BB, The effect of obstructions and thermal in laminar-flow systems. *Journal of Hygiene* 72:1974;415-423.
[2] Zoon WAC, van der Heijden MGM, Loomans MGLC, Hensen JLM, On the applicability of the laminar flow index when selecting surgical lighting. *Building and Environment* 45:2010;1976-1983.
[3] Sadrizadeh S, Holmberg S, Surgical clothing systems in laminar airflow operating room: A numerical Assessment. *Journal of Infection and Public Health* 7:2014;508-516.
[4] Sadrizadeh S, Holmberg S, Tammelin A, A numerical investigation of vertical and horizontal laminar airflow ventilation in an operating room. *Building and Environment* 82:2014;517-525.
[5] Wang C, Sadrizadeh S, Holmberg S, Influence of the shape of surgical lamps on the airflow and particle distribution in operating rooms. *Proceedings of the 11th International Conference on Air Distribution in Rooms*, May 24-27, 2009, Busan Korea.
[6] Refaie R, et al., The effect of operating lights on laminar flow. *The Bone and Joint Journal* 99:2017;B1061-1066.
[7] Cao G, et al., Do surgeons and surgical facilities disturb the clean air distribution close to a surgical patient in an orthopedic operating room with laminar air flow? *American Journal of Infection Control* (in press).
[8] McNeill J, Hertzberg J, Zhai Z, Experimental investigation of operating room air distribution in a full-scale laboratory chamber using particle image velocimetry and flow visualization, Journal of Flow Control, Measurement, and Visualization, 1:2013;24-32.
[9]Hermann-Rietschel-Institut (HRI), and provided online by the German Federal Ministry for Economic Affairs and Energy (https://blogs.tu-berlin.de/hri_op-luft/2019/01/04/closer-look-on-lamp-shapes/).
[10] Chow TT, Wang J, Dynamic simulation on impact of surgeon bending movement on bacteria-carrying particles distribution in operating theatre. *Building and Environment* 57:2012;68-80.
[11] Sadrizadeh S, Afshari A, Karimipanah T, Hakansson U, Nielsen PV, Numerical simulation of the impact of surgeon posture on airborne particle distribution in a turbulent mixing operating theatre, *Building and Environment* 110:2016;140-147.
[12] Brohus H, Balling KD, Jeppsen D, Influence of movements on contamination in an operating room *Proceedings of Indoor Air 2005* 3106-3111.
[13] Wong KY, et al, Effects of staff movement and air change rate on the airflow fields in an hospital's operating room. *IJCTA* 10:2017;265-275.
[14] Sadrizadeh S, Tammelin A, Ekolind P, Holmber S, Influence of staff number and internal constellation on surgical site infection in an operating room. *Particuology* 13:2014;42-51.

[15] Pokrywka P, Byers K, Traffic in the operating room: A review of factors influencing air flow and surgical wound contamination. *Infectious Disorders – Drug Targets* 13:2013;156-161.
[16] Tumia N, Ashcroft GP, Convection warmers – A possible source of contamination in laminar airflow operating theatres? *Journal of Hospital Infection* 52:2002;171-174.
[17] Smith EB, et al., The effect of laminar air flow and door openings on operating room contamination. *The Journal of Arthroplasty* 28:2013;1482-1485
[18] Saarinen PE, Kalliomaki P, Tang JW, Koskela H, Large eddy simulation of air escape through a hospital isolation room single hinged doorway – validation by using tracer gases and simulated smoke videos. *PLOS One* 10:2015;1-19.
[19] Kalliomaki P, Saarinen P, Wang JW, Koskela H, Airflow patterns through single hinged and sliding doors in hospital isolation rooms, *International Journal of Ventilation*, 14:2015;111-126.
[20] Villafruela JM, San Jose, JF, Castro F, Zarzuelo A, Airflow patterns through a sliding door during opening and foot traffic in operating rooms. *Building and Environment* 109:2016;190-198.
[21] Mears SC, Blanding R, Belkoff SM, Door opening affects operating room pressure during joint arthroplasty, *Orthopedics* 38:2015;e991-e994.
[22] Chang L, Tu S, Ye W, Zhang X, Dynamic simulation of contaminant in leakage produced by human walking into control room, *International Journal of Heat and Mass Transfer* 113;2017:1179-1188.
[23] Scaltriti S, et al., Risk factors for particulate and microbial contamination in air in operating theatres. *Journal of Hospital Infection* 66:2007;320-326.
[24] Wang J, Chow TT, Numerical investigation of influence of human walking on dispersion and deposition of expiratory droplets in airborne infection isolation rooms. *Building and Environment* 46:2011;1993-2002.
[25] Inthavong K, et al., A smoke visualization technique for wake flow from a moving human manikin, *Journal of Visualization*, 20;2017:125-137.
[26] Sadrizadeh S, et al., Airborne particle dispersion to an operating room environment during sliding and hinged door opening. *Journal of Infection and Public Health* (in press).
[27] Teter J, et al., Assessment of operating room airflow using particle counts and direct observation of door openings. *American Journal of Infection Control* 45:2017;477-482.
[28] Perez P, et al., Door openings in the operating room are associated with increased environmental contamination. *American Journal of Infection Control*, 46: 2018;954-956.
[29] Lydon GP, Ingham DB, Mourshed MM, Ultra clean ventilation system performance relating to airborne infections in operating theatres using CFD modelling. *Building Simulation* 7:2014;277-287.
[30] Zhou B, Ding L, Li F, Xue K, Nielsen PV, Xu Y, Influence of opening and closing process of sliding door on interface airflow characteristic in operating room, *Building and Environment* 144:2018;459-473.
[31] Elghobashi S, Expert Declaration in General Causation and Garreis v. 3M (Plaintiff)
[32] Shirozu K, et al., Effects of forced air warming on airflow around the operating table. *Anesthesiology* 128:2018;79-84.
[33] Ufat H, Kaynakli O, Yamankaradeniz N, Yamankaradeniz R, Three-dimensional air distribution analysis of different outflow typed operating rooms at different inlet velocities and room temperatures. *Advances in Mechanical Engineering* 9:2017;1-12.
[34] Abraham JP, Expert Declaration in General Causation and *Gareis v. 3M*

[35] Forliti DJ, Tang BA, Strykowski PJ, An experimental investigation of planar countercurrent turbulent shear layers, Journal of Fluid Mechanics 530:2005;241-264.
[36] Strykowsky PJ, Forliti DJ, Flow control applications using countercurrent shear, International Symposium on Recent Advances in Experimental Fluid Mechanics, Kampur, India, December 18-20, 20002.

MATERIALS CONSIDERED

Abraham General Causation and *Gareis* Reports

Elghobashi General Causation and *Gareis* Reports

Abraham General Causation and *Gareis* deposition and trial testimony

Elghobashi General Causation and *Gareis* deposition and trial testimony

Photographs of Trombley Operating Room, 3MBHPF00100512-3MBHPF00100782

Bay Park Community Hospital production, Bay_Park_0000001 - Bay_Park_0000044

Jarvis *Trombley* expert report

All references cited herein

Supplemental videos from Saarinen PE, Kalliomaki P, Tang JW, Koskela H, Large eddy simulation of air escape through a hospital isolation room single hinged doorway – validation by using tracer gases and simulated smoke videos. *PLOS One* 10:2015;1-19.

Supplemental videos from Villafruela JM, San Jose, JF, Castro F, Zarzuelo A, Airflow patterns through a sliding door during opening and foot traffic in operating rooms. *Building and Environment* 109:2016;190-198.

Supplemental videos from Inthavong K, et al., A smoke visualization technique for wake flow from a moving human manikin, *Journal of Visualization*, 20;2017:125-137.

Airflow videos provided by Technische Universitat Berlin Hermann-Rietschel-Institut